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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,406	06/11/2007	Jing X. Kang	64624(51588)	8352
71284	7590	10/17/2008	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			CHEN, SHIN LIN	
P.O. BOX 55874				
BOSTON, MA 02205			ART UNIT	PAPER NUMBER
			1632	
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			10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,406	Applicant(s) KANG, JING X.	
	Examiner Shin-Lin Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16, drawn to an isolated nucleic acid molecule comprising a sequence encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid, for example the enzyme is a *C. elegans* fat-1 gene, wherein the sequence includes at least one optimized codon, an expression vector comprising said nucleic acid, and a host comprising said vector or nucleic acid.

Group II, claim(s) 17-19, drawn to a non-human transgenic animal comprising the nucleic acid of claim 1, wherein the non-human transgenic animal is a mammal.

Group III, claim(s) 20 and 21, drawn to a food product or dietary supplement comprising the non-human transgenic animal of claim 17 or tissue or processed part thereof, and a method of improving the content of n-3 fatty acid in a subject's diet by administering to the subject the food product or dietary supplement.

Group IV, claim(s) 22 and 23, drawn to a method of treating a patient having cancer by administering the patient a therapeutically effective amount of the nucleic acid molecule of claim 1.

Group V, claim(s) 24-26, drawn to a method of inhibiting neuronal cell death in a subject by administering to the subject the nucleic acid molecule of claim 1.

Group VI, claim(s) 27 and 28, drawn to a method of treating a subject having a condition associated with an insufficiency of n-3 polyunsaturated fatty acid (PUFA) or an imbalance in the ratio of n-3:n-6 PUFAs by administering to said subject the nucleic acid molecule of claim 1.

Group VII, claim(s) 29, drawn to a method of treating a subject having received a transplant by administering to the subject or the transplant the nucleic acid molecule of claim 1.

Group VIII, claim(s) 17-19 and 30-37, drawn to a non-human transgenic animal comprising the nucleic acid of claim 1, wherein the non-human transgenic animal is a transgenic fish.

Group IX, claim(s) 17-19 and 38-45, drawn to a non-human transgenic animal comprising the nucleic acid of claim 1, wherein the non-human transgenic animal is a transgenic bird.

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2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The putative common special technical feature is the nucleic acid molecule comprising a sequence encoding an enzyme that desaturates an n-6 fatty acid to a corresponding n-3 fatty acid, for example the gene for the enzyme is a *C. elegans* fat-1 gene. Browse et al., 2002 (US 20020170090 A1) discloses the nucleotide sequence of the *C. elegans* fat-1 cDNA sequence and the deduced amino acid sequence of the FAT-1 polypeptide in Figure 1. The FAT-1 polypeptide desaturates an omega-6 fatty acid to a corresponding omega-3 fatty acid ([0008]). A fat-1 cDNA was incorporated into pYX232 yeast expression vector under the control of the triosephosphate isomerase promoter and the fat-1 vector was transformed into yeast cells having omega-6 fatty acyl substrate ([0134]). Further, Okuda et al., 2005 (US Patent No. 6,936,707 B2) teaches that "the amount expressed of a gene can be enhanced by replacing with a translation codon (optimization of codon) of an amino acid that is highly frequently used in the living body in which the DNA molecule is to be expressed (Detailed Description Text (15)). It would be obvious to optimize the translation codon of the fat-1 gene. Therefore, no special technical feature has been contributed by the instant invention over the prior art. Thus, Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If group VI is elected, the species are arrhythmia, cardiovascular disease, cancer, an inflammatory disease, an autoimmune disease, a malformation or threatened malformation of the retina or brain, diabetes, obesity, a skin disorder, a renal disease, ulcerative colitis, Crohn's disease, and chronic obstructive pulmonary disease.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Claims 27 and 28

The following claim(s) are generic: claim 27.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species are drawn to totally different diseases that differ physiologically and pathologically. They do not share common properties.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.
/Shin-Lin Chen/
Primary Examiner
Art Unit 1632